

MAR - 3 1997

> 510(k) SUMMARY <
SAFFETY & EFFECTIVENESS SUMMARY

**BIOSEARCH SYRINGE
FLUSHING/CLEANING PUMP FOR
BIOSEARCH ENDOSCOPIC INSTRUMENTS**

Manufactured / Sold by:

**Biosearch Medical Products, Inc.
35 Industrial Parkway
P.O. Box 1700
Somerville, NJ. 08876 {USA}**

**Telephone : 1-908-722-5000
Fax : 1-908-722-5024**

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New Product Development Coordinator**

12/2/96
date submitted

**Biosearch Medical Products, Inc. P.O. Box 1700 Somerville, NJ. 08876-1276 (USA)
TEL: 908-722-5000 FAX: 908-722-5024**

Biosearch Medical Products, Inc. -- 510(k) submission for: BIOSEARCH SYRINGE FLUSHING/CLEANING PUMP FOR BIOSEARCH ENDOSCOPIC INSTRUMENTS

INTENDED USE STATEMENT: The Syringe Flushing/Cleaning Pump is intended to clean the Biosearch Endoscopic Instruments.

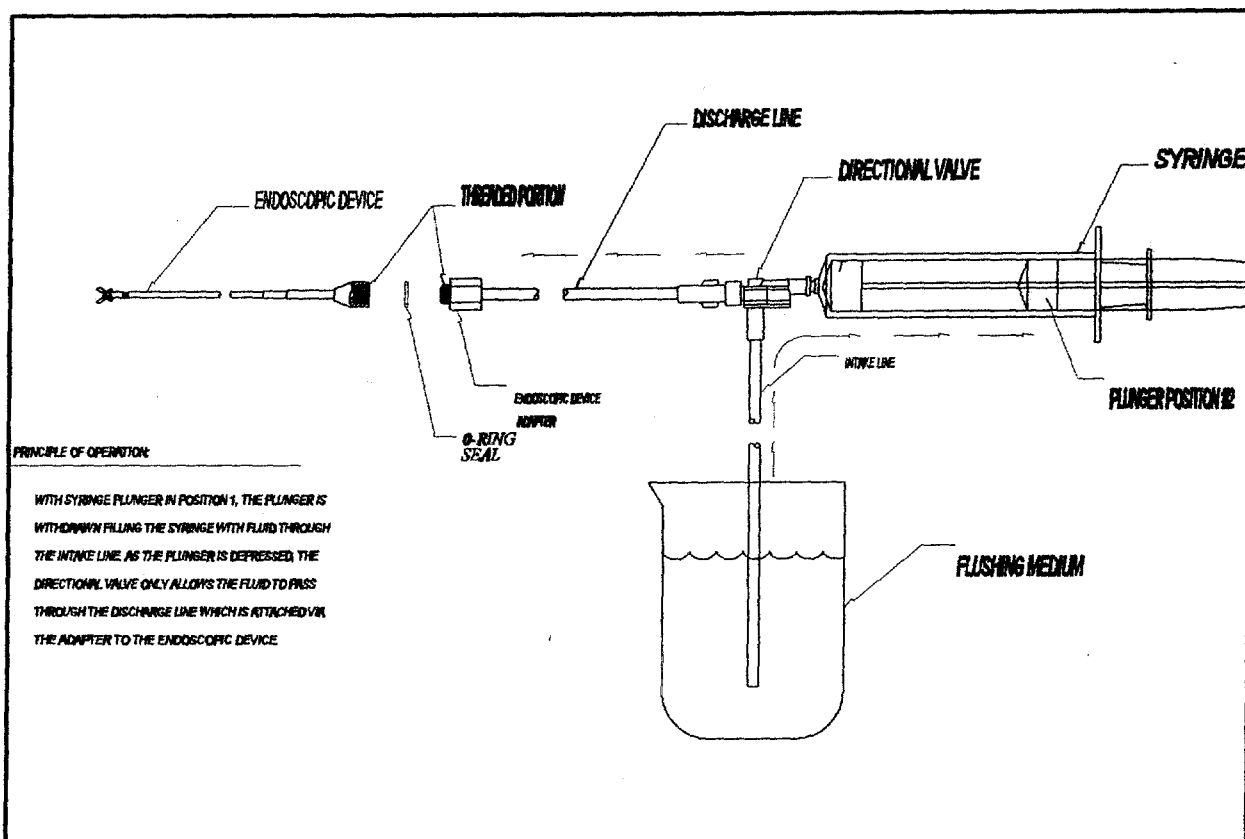
The Syringe Flushing/Cleaning Pump is a device that helps remove debris that may get trapped inside the Biosearch Endoscopic Instrument.

DESCRIPTION OF THE DEVICE:

The Disposable Syringe Flushing/Cleaning Pump for Biosearch Endoscopic Instruments, is a similar design to an existing legally marketed device. It is composed of a variety of medical grade plastics.

The threaded connector is especially designed to fit the flushing port of the Biosearch Endoscopic device which impedes water leakage during the cleaning process.

The dual check valve is an important feature because it provides an efficient transfer of the water, and/or cleaning fluid. This will provide a sanitary environment for the medical health professional to perform the extensive cleaning of the Biosearch Endoscopic Instruments.



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FLUSHING/CLEANING PUMP FOR BIOSEARCH ENDOSCOPIC INSTRUMENTS**

EQUIVALENCE MATRIX
(COMPARING CLEANING ADAPTERS FUNCTIONS)

NAME & 510(K) No.	For Cleaning Endoscopic Instruments	Connects to the proximal port	Uses a syringe to pump cleaning fluid
BIOSEARCH "BiosearchFlushing/Cleaning Pump for Biosearch Endoscopic Instruments" {This submission}	YES	YES	YES
MILL-ROSE "Cleaning Adapter" {k922204}	YES	YES	YES

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NO PATIENT CONTACT

<u>MATERIAL</u>	<u>TEST DATE</u>	<u>TEST PERFORMED</u>	<u>RESULTS</u>
PolyVinyl Chloride	Vendor Supplied	USP tests for Systemic Injection Test, Intracutaneous Injection Test, Implantation test	Meets the requirements of USP Class VI Plastic
Polyurethane Tecothane™ TT-1080A	6/26/91-6/28/91	MEM Elution Test	Meets the requirements of the Elution Test, USP XXII for the Elution Test
Polyurethane Tecothane™ TT-1080A	6/14/91-6/29/91	Biological Test for Plastics Class VI	Meets the requirements of the USP XXII for the Biological Test of Plastic
Polyurethane Pellethane 2363 Series	Vendor Supplied	Acute Systemic Toxicity, Intracutaneous Toxicity, Implantation Test	Meets the requirements of the USP Class XI
Polycarbonate HPS2-1125	Vendor Supplied	Cytotoxicity, Hemolysis, Implantation, USP Class V Extractables, USP Physicochemical-Plastics	Meets the requirements of Class VI in Vivo & in Vitro Biological Reactivity, USP Physicochemical-Plastic
Dow Corning RX50 CT Silastic Ribbon		Cytotoxicity, Hemolysis, Implantation, USP Class V Extractables, USP Physicochemical-Plastics	Meets the requirements of Class VI in Vivo & in Vitro Biological Reactivity, USP Physicochemical-Plastic

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Alpha PVC 2212/7 118 RSI Clear	6/20/88 6/18/84-6/25/84 6/20/84	USPXX Systemic Injection Test USPXX Intramuscular implantation, USP XX Intracutaneous Test, Direct Exposure Cytotoxicity Test	Meets the USP Class VI requirements
Cyrolite® G20-300-001	Vendor Supplied	Systemic Toxicity, Intracutaneous Toxicity, MEM Elution, Hemolysis, Pyrogen, Guinea Pig Max. Implantation Test	Meets the USP Class VI requirements
Cyrolite® G20-100-001	Vendor Supplied	Systemic Toxicity, Intracutaneous Toxicity, Implantation Test Hemolysis, MEM Elution Pyrogen, Guinea Pig Max.	Meets the USP Class VI requirements Meets the USP Class VI requirements
Radel R-5100	Vendor Supplied	Systemic Toxicity, Intracutaneous Toxicity, Implantation Test	Meets the USP Class VI requirements
Silastic Medical Grade{7-4735, 7-4750, 7-4765}	Vendor Supplied	Hemolysis, Intracutaneous Injection, Systemic Injection Intramuscular Implant	Meets the USP Class VI Plastic Tests
Silastic Biomedical Grade Liquid {Q-7-480,6860}	Vendor Supplied	Hemolysis, Skin Sensitization USP Class V Extractables	Passes the Hemolysis Skin Sensitization,& USP Class V Extractables Tests